

# Bipartisan bill aims to reform step therapy, ensure timely care

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The “Safe Step Act,” a bipartisan bill introduced in both the U.S. Senate and House of Representatives, has the AMA’s support because it addresses concerns related to patient safety, negative clinical outcomes and interruptions in care caused by health insurance company step-therapy protocols.

Step therapy, sometimes called “fail first” therapy, is a form of utilization management that requires patients to first try and fail lower-cost tests, drugs or other treatments preferred by payers before moving on to options recommended by a patient’s physician.

“Medication step-therapy protocols, and more broadly utilization-management programs, can create significant barriers for patients by delaying the start or continuation of necessary medical treatment, which can negatively affect patient health outcomes,” AMA Executive Vice President and CEO James L. Madara, MD, wrote in letters to House and Senate sponsors of the new legislation.

Another health plan utilization-management or cost-control process is prior authorization, which requires physicians to get approval before a prescribed treatment, test or medical service qualifies for payment. Step therapy and prior authorization pose significant administrative burdens for practices and delay patients from receiving necessary care.

## Bill aligns with reform principles

“While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances may necessitate an alternative treatment,” Dr. Madara’s letters say. “Furthermore, forcing patients to abandon already effective treatment and repeat a therapy that has been proven ineffective delays care and may result in negative health outcomes.”

In recognition of these adverse impacts, the AMA and other organizations developed “Prior Authorization and Utilization Management Reform Principles” that promote commonsense concepts to improve prior authorization, step therapy and other utilization-management programs.

The principles require protocols to be clinically valid, ensure continuity of care, and be fair and transparent.

The “Safe Step Act” aligns with these principles in that it would require group health plans to provide an exception process for step-therapy protocols when the:

- Plan’s required treatment has been ineffective.
- Required treatment is expected to be ineffective and delay effective treatment leading to irreversible consequences.
- Treatment will cause or is likely to cause an adverse reaction to the patient.
- Treatment is expected to prevent the patient from working or other daily activities.
- Patient’s condition is stable based on a prescription-medication regimen already selected.

The bill would also require insurers to implement a clear and transparent process to request an exception to a step-therapy protocol, and it sets deadlines for responses to regular and urgent exemption requests.

“By creating this process, the ‘Safe Step Act’ helps ensure that patients have timely access to treatment and reduces administrative costs to the health care system,” Dr. Madara wrote.

## Prior auth reforms supported

The AMA also supports the bipartisan “Improving Seniors’ Timely Access to Care Act” that was reintroduced this year.

The legislation would improve access to care by streamlining and standardizing the way Medicare Advantage plans use prior authorization and increasing oversight and transparency around prior authorization.

Learn how the AMA is leading prior authorization reform.